K111695

510(k) Summary

APR - 2 2012

Cook Biotech Incorporated

Hybrid Graft

Manufacturer Name: Cook Biotech Incorporated
1425 Innovation Place
West Lafayette, Indiana 47906
Telephone: +1 (765) 497-3355
FAX: +1 (765) 807-7709

Official Contact: Perry W. Guinn

DEVICE NAME AND CLASSIFICATION

Trade/Proprietary Name:	Hybrid Graft
Common Name:	Surgical Mesh
Classification Regulations:	Class II, 21 CFR §878.3300 (79FTL)

INTENDED USE:

The Hybrid Graft is for implantation to reinforce soft tissues where weakness exists. Indications for use include the repair of a hernia or body wall defect requiring the addition of a reinforcing or bridging material to obtain the desired surgical result. The graft is supplied sterile and is intended for one-time use.

DEVICE DESCRIPTION:

The Hybrid Graft is composed of a bioabsorbable, extracellular collagen matrix (Small Intestinal Submucosa, SIS) and a polypropylene mesh. The collagen matrix is identical to the predicate SIS Hernia Repair Device (K974540, K062697), manufactured by Cook Biotech Incorporated. The polypropylene mesh is similar to the predicates PROCEED™ Ventral Patch (K061533) and ULTRAPRO® Mesh (K033337), both manufactured by Ethicon, Incorporated. The Hybrid Graft is similar to both PROCEED and ULTRAPRO in that all are made of a composite of a bioabsorbable or collagen-based and synthetic (polypropylene) component. The polypropylene mesh in the Hybrid Graft is layered between six (6) layers of SIS on the side facing the viscera and two (2) layers of SIS on the side facing the body wall. The device is packaged in a vacuum pressed (dried), laminated state and supplied sterile in a sealed double pouch system.

EQUIVALENCE TO MARKETED DEVICES

The Hybrid Graft is similar with respect to intended use and with respect to materials and technological characteristics to the predicate devices in terms of section 510(k) substantial equivalence, as shown through bench and biocompatibility testing:

Bench Testing
Finished devices were tested for mechanical performance as follows:

- Suture retention
- Ultimate tensile strength
- Diaphragmatic burst strength

The mechanical performance of the Hybrid Graft is adequate for the application.

Biocompatibility testing

The SIS material comprising the Hybrid Graft was tested under ISO 10993 standards as follows:

- Genototicity
- Direct contact *in vitro* hemolysis
- Cytotoxicity
- Muscle implantation
- Acute intracutaneous reactivity
- ISO sensitization
- Acute systemic toxicity
- Pyrogenicity
- LAL endotoxins
- Subchronic toxicity

The Hybrid Graft was tested under ISO 10993 standard under the following:

- Cytotoxicity

A Biocompatibility Assessment from NAMSA™ attesting to the biocompatibility of the Hybrid Graft was provided for this submission.

The results of the biocompatibility testing show that the Hybrid Graft met the requirements of the ISO 10993 standards and is substantially equivalent to its predicates.

Substantial Equivalence

See Table 1 below for a comparison of the subject device and its predicates.

Table 1 – Substantial Equivalence Table

Device	Hybrid Graft	SIS Hernia Repair Device	SurgiSIS Mesh	PROCEED™ Ventral Patch	ULTRAPRO® Mesh
Manufacturer	Cook Biotech Incorporated	Cook Biotech Incorporated	Cook Biotech Incorporated	Ethicon, Incorporated	Ethicon, Incorporated
510(k) Number	K111695	K974540, K062697	K980431	K061533	K033337
Intended Use	To be implanted to reinforce soft tissues where weakness exists. Indications for use include the repair of a hernia or body wall defect requiring the addition of a reinforcing or bridging material to obtain the desired surgical result.	To be implanted to reinforce soft tissues where weakness exists. Indications for use include the repair of a hernia or body wall defect.	For implantation to reinforce soft tissue.	For the repair of hernias or other abdominal fascial defects that require the addition of a reinforcing or bridging material to obtain the desired surgical results.	For the repair of hernias and other abdominal fascial deficiencies that require the addition of a reinforcing or bridging material to obtain the desired surgical result.
Material	Small intestinal submucosa Primarily Types I, III, IV and VI collagen and polypropylene	Small intestinal submucosa Primarily Types I, III, IV and VI collagen	Small intestinal submucosa Primarily Types I, III, IV and VI collagen	Oxidized regenerated cellulose (ORC), polypropylene	Poliglecaprone-25 and polypropylene
Dimensions	15 cm x 22 cm to 30 cm x 30 cm, 15 cm diameter	5 cm x 8 cm to 20 cm x 30 cm	0.6 cm x 5 cm to 7 cm x 20 cm	5 cm x 10 cm to 30.5 cm x 30.5 cm	7.6 cm x 15 cm to 30 cm x 30 cm
Thickness	0.1 to 2.0 mm	0.1 to 1.5 mm	0.1 to 2.0 mm	N/A	N/A

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Room –WO66-G609
Silver Spring, MD 20993-0002

Cook Biotech, Incorporated
% Mr. Perry W. Guinn
Vice President, Regulatory Affairs and Quality Assurance
1425 Innovation Place
West Lafayette, Indiana 47906-4224

APR - 2 2012

Re: K111695
Trade/Device Name: Hybrid Graft
Regulation Number: 21 CFR 878.3300
Regulation Name: Surgical mesh
Regulatory Class: II
Product Code: FTL
Dated: March 14, 2012
Received: March 15, 2012

Dear Mr. Guinn:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21

CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please go to http://www.fda.gov/AboutFDA/CentersOffices/CDRH/CDRHOffices/ucm115809.htm for the Center for Devices and Radiological Health's (CDRH's) Office of Compliance. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

For Bram D. Zuckerman

Mark N. Melkerson
Director
Division of Surgical, Orthopedic
and Restorative Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

K111695

Indications for Use

510(k) Number (if known):

Device Name: **Hybrid Graft**

Indications For Use:

The Hybrid Graft is intended to be implanted to reinforce soft tissues where weakness exists. Indications for use include the repair of a hernia or body wall defect requiring the addition of a reinforcing or bridging material to obtain the desired surgical result. This graft is supplied sterile and is intended for one-time use.

Prescription Use __X____ (Part 21 CFR 801 Subpart D) AND/OR Over-The-Counter Use _____ (21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

David Kwan for MKM

(Division Sign-Off)
Division of Surgical, Orthopedic,
and Restorative Devices

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